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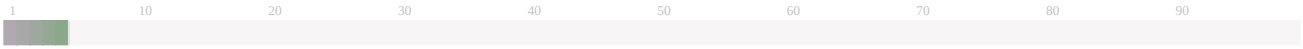

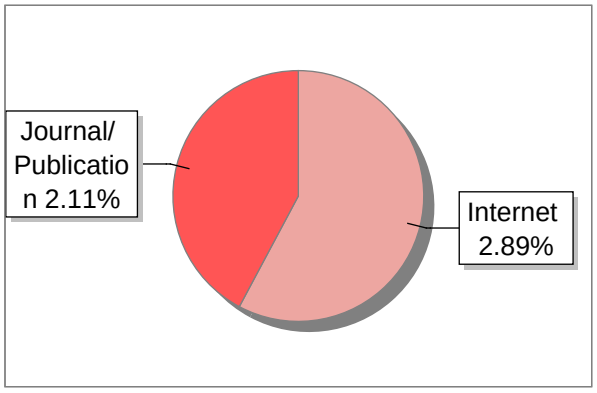

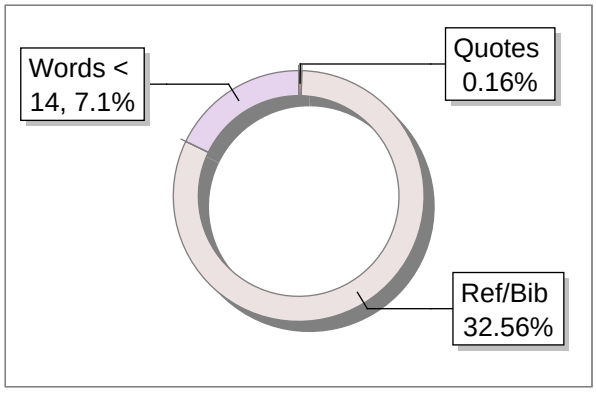

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DEVELOPMENT, EVALUATION AND VALIDATION OF REHABILITATION TECHNIQUESFOR EARLY RECOVERY OF POST SURGICAL BRAIN INJURY PATIENTS

A SYNOPSIS

Submitted for the Registration for the Degree

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PHYSIOTHERAPY

Faculty of Physiotherapy and Allied Health Sciences

by

AISHWARYA RAI

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Enrollment Number: 2003000035705

Under the Supervision of

Prof. (Dr.) Jasmine Anandabai

Faculty of Physiotherapy and Allied Health Sciences

JYOTIRAO PHULE SUBHARTI COLLEGE OF PHYSIOTHERAPY

Swami Vivekanand Subharti University

(NAAC Accredited grade "A" University)

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INTRODUCTION

A traumatic brain injury (TBI) is a non-degenerative, non-congenital insult to the brain from external mechanical forces either leading to temporary or permanent impairment of cognitive, physical, psychosocial functions with may be associated, diminished or altered state of consciousness in patients.

It is one of the leading causes of debility and disability in present-times. It is estimated that about 1.5-2 million people are injured every year and nearly a million succumb to death in India alone. [1] It is a major cause of preventable death and disability.

The requirement for insurance preauthorization, a lack of beds in rehabilitation centers, the facility's remote location from the patient's home and family, the inconsistent quality of rehabilitation services, and the reluctance of facilities to admit patients who might not be able to return home after rehabilitation are some of the obstacles to receiving comprehensive inpatient rehabilitation.

Research demonstrates that while many patients with moderate to severe traumatic brain injury (TBI) benefit from extensive interdisciplinary inpatient rehabilitation, the majority are discharged home or to skilled nursing facilities, which frequently do not offer intensive, comprehensive, or specialized therapy and only provide a few opportunities for re-evaluation of such individuals.

Adherence to evidence-based treatment guidelines have been shown to improve TBI outcomes.[4]

Clinical guidelines offer suggestions on how medical personnel should treat patients with specific illnesses. They can address any area of a disease and contain suggestions for providing guidance and information, for preventing and diagnosing conditions together with their treatments, for appropriate long-term management, and are made to assist in the decision-making processes involved in patient care. The primary source of evidence-based care, clinical evidence and research literature, form the basis of a guideline's content.

The aim of clinical guidelines is to improve the quality of care by translating new research findings into practice. There is evidence that the following characteristics contribute to their use: inclusion of specific recommendations, sufficient supporting evidence, a clear structure and an attractive layout in the process of formulating recommendations, implicit norms of the target users should be taken into account.

A reliable central body should create the guidelines as part of a planned and organized program. Guidelines could serve as a model for regional protocols, therapeutic pathways, and interprofessional agreements to facilitate their implementation[5].

- To reduce unwarranted variation in practice;
- To offer a more rational basis for referral;
- To act as a focus for quality control, including audit;
- To highlight the shortcomings of existing literature and suggest appropriate future research[6].
- To promote efficient use of resources;
- To describe appropriate care based on the best available scientific evidence and broad consensus.

TRAUMATIC BRAIN INJURIES AND QUALITY OF LIFE

The majority of concepts of quality of life (QoL) include both objective and subjective dimensions. The objective aspect of QoL after traumatic brain injury (TBI) concentrates on patients' functioning in physical, psychological, social and cognitive domains. The subjective component refers to life satisfaction and individual evaluation of life as a whole or in the domains[8].

Historically perceived as an abrupt, violent incident with temporary disability, traumatic brain injuries (TBIs) have long-lasting, even lifelong, effects. Even though the death rate has decreased, many people who have survived severe traumatic brain injury (TBI) need extended rehabilitation and may experience long-term cognitive, psychological, and physical problems. Furthermore, chronic effects have been found in a percentage of cases that were previously categorized as moderate or mild, in addition to severe traumatic brain injury. In addition to having an impact on survivors' and their families' daily lives, this load has associated societal and financial costs[9].

Patients of all ages often present with a heterogeneous combination of symptoms that can progress in nature and involve multiple pathophysiological mechanisms after a brain injury of varying severity.[10] These biological mechanisms can cause excitotoxicity, apoptosis, inflammatory events, seizures, demyelination, white matter pathology, and neurodegeneration, resulting in prolonged motor and cognitive deficits.[11] Some TBI symptoms may occur early and improve or worsen over time, whereas others may develop later in the course of recovery.[12] Although symptoms resolve for a majority of persons who experience mTBI in ~3 months, some continue to experience symptoms at or beyond 1 year post-injury.[13] Estimates indicate that between 15% and 30% of persons who experience an mTBI suffer symptoms long after exposure,[14-18] as indicated by imaging findings, age, population studied, time of initial assessment, and patient presentation.[19] Although these percentages are likely an underestimate, studies are beginning to reveal that even a single mTBI might manifest as a measurable cognitive impairment as early as 3 months after injury.

REVIEW OF LITERATURE

1. **In (1999) A nonfederal, non-advocate, 16-member panel where no authors were listed** representing the fields of neuropsychology, neurology, psychiatry, behavioral medicine, family medicine, pediatrics, physical medicine and rehabilitation, speech and hearing, occupational therapy, nursing, epidemiology, biostatistics, and the public concluded that TBI is a condition that is extremely important to public health. Because mild TBI is notably underdiagnosed, there will likely be an even bigger social cost. Prevention is crucial because of the high death toll from traumatic brain injury and the lack of a treatment. The assessment of rehabilitation strategies for the cognitive and behavioral effects of traumatic brain injury, however, was the main focus of this meeting. There is evidence to support the application of specific behavioral and cognitive rehabilitation techniques for TBI patients. Funding for TBI research needs to be expanded in order to duplicate this work in bigger, more conclusive clinical trials[32].
2. **Denes (2005)** suggested that rehabilitation treatment of patients with severe traumatic brain injury is suggested in centers, where special team is available for the patients with multifunctional impairments. Nowadays, only one third of these patients are treated by rehabilitation centers in Hungary. Establishing new centers, development of the existing units, improvement the outpatient or community based rehabilitation facilities are suggested in order to improve the rehabilitation outcome of patients with severe traumatic brain injury[45].
3. **Burtin Chris et al (2009)** concluded that In critically ill intensive care unit survivors, early exercise training improved muscle force, self-perceived functional status, and functional exercise capacity upon hospital discharge. [35].
4. **Tomaszeuski et al (2011)** concluded that that a rehabilitation program controlled by a strategic plan, with the cooperation of the patient, is more effective in improving the quality of life, as the patient is more self-motivated to individually designed objectives[31].
5. **Pachalska et al (2012)** concluded that A rehabilitation program controlled by a strategic plan, in collaboration with the patient treated subjectively is more effective in improving the quality of life, since the cooperating patient is more motivated to carry out individually designed goals. A rehabilitation program based on a strategic plan is worthy of recommendation for the treatment and improvement of patients after cranio-cerebral trauma[30].
6. **Engel et al (2013)** determined that implementing a planned, structured effort to improve the quality of early mobility in ICUs can lead to better results and lower costs for ICU patients in various healthcare systems. The implementation of an ICU early mobilization quality improvement program led to shorter hospital and ICU stays at all three facilities, as well as lower rates of delirium and sedative requirements for patients participating in the Johns Hopkins ICU early mobility program.[37].
7. **Lord Robert K et al (2013)** concluded that U.S. hospitals may experience net financial savings by investing in an ICU early rehabilitation program, according to a financial model based on real experience and publicly available data. The estimated net cost of adopting such a program is low, even with the most conservative assumptions, as compared to the significant gains in patient outcomes that ICU early rehabilitation programs have shown.[38].

8. **Karol (2014)** concluded that Neurorehabilitation requires a team effort. Over time the nature of teams has evolved from single discipline work through multi-disciplinary and inter-disciplinary teams to trans-disciplinary teams. It is the gold standard for teams in neurorehabilitation because they entail more integrated service delivery than do other teams. Trans-disciplinary teams also represent a more persons-centered approach. To initiate a trans-disciplinary model, team members must have excellent communication and shared decision making including persons with brain injury. Leadership must address staff selection, scope of practice and role-release. Otherwise, the model will fail due to peer pressure and institutional or program cultural variables[44].
9. **Popernack et al (2014)** determined that while the degree of disability varies according to the mechanism and severity of the damage, a range of mental and physical deficiencies may be noticeable years after the injury. The pathophysiology of moderate to severe traumatic brain injury (TBI), its accompanying consequences, and chances to enhance patient outcomes by employing acute treatment and rehabilitation techniques are all covered in this article. A cooperative effort is required to support impacted children's smooth transition from acute treatment through long-term rehabilitation in order to address the numerous obstacles faced by TBI survivors and their families, including heavy financial and emotional burdens.[23]
10. **Lorenz et al (2015)** concluded that even after a severe brain injury, when the right rehabilitation is provided at the right time, the "rest of life" journey can be a positive one for many. Severe brain injury can lead to a "new normal" as patients regain skills, find new meaning and in life, and take on new family, volunteer, and work roles. It is estimated that 15 to 30% of people with even a mild TBI can result in long term functional impairments. Lifelong difficulties may impact an individual's capacity to work, carry out everyday tasks like clothing and bill-paying, engage in community activities, and/or fulfill familial responsibilities throughout the chronic phase of acquired brain injury, regardless of the etiology.[20].
11. **Hodgson et al (2016)** determined that it was feasible and safe to give early goal-directed mobilization within a randomized controlled trial, and that this led to an increase in the amount and duration of physical activities. [42].
12. **Andelic et al (2018)** concluded that Functional limitations persist even decades after moderate and severe TBI, with poorer prognosis for females and persons who were depressed at the 10-year follow-up. It is important to emphasize the creation and assessment of focused long-term follow-up programs as well as these groups' access to rehabilitation services. Better community inclusion in spite of stable functional limits highlights the importance of long-term sickness and adversity adaptability.[28].
13. **Marklund et al (2019)** concluded that Regardless of the severity, traumatic brain injury (TBI) can have long-lasting effects that range in degree of permanent disability. Since SRCs are a mild traumatic brain injury (TBI), there is growing worry about them. To minimize the risk of worsening and maximize recovery, management measures must be taken both immediately after the injury, via quick evaluation on the sidelines, and later on. Advances in neuro-critical care monitoring facilitate the identification of several aggravating variables for traumatic brain injury (TBI) patients, hence optimizing treatment outcomes. Rehabilitation is necessary after the initial

stages of an injury to aid with healing. Novel approaches to cognitive rehabilitation could be significant, but additional controlled trials are needed to assess their impact in the future.[21].

14. **Schuzman et al (2020)** concluded that at the time of ICU discharge, patients who had taken part in an ICU mobility program had improved functional status. Better results on the mobility tests and enhanced maximum voluntary breathing performance were two more advantages of the program.[43].
15. **Lang et al (2020)** concluded that There were notable international consistent patterns in the clinical practice guidelines for early mobilization, despite notable differences in their methodological quality. Gaps concerning patient selection, dose, team culture, and competence should be filled by future study. Involving patients and families in the formulation process and providing resources to promote implementation while taking recognized facilitators and barriers into account should be the main goals of future clinical practice recommendations in this field.[36].
16. **Rauen et al (2020)** concluded that One third of patients even ten years after TBI, suffer from unsatisfactory outcome with psychiatric sequelae. Thus, an early neuropsychiatric assessment after TBI is necessary and need to be installed in future TBI guidelines[24].
17. **Rauen et al (2021)** concluded that aging-related traumatic brain injury (TBI) had no effect on the result of HRQoL in males, but it did in females, indicating that female brains are less resilient to aging-related traumatic injury. Thus, after traumatic brain injury (TBI), older females require ongoing follow-ups to identify neuropsychiatric consequences that may limit their quality of life. Additional research is required to determine the mechanisms underlying this as-yet-unknown phenomena.[40].
18. **Forslund et al (2021)** concluded that longer time, male gender, employment pre-injury, and shorter length of post-traumatic amnesia were significant predictors of better physical health trajectories; longer time, male gender, and employment pre-injury were significant predictors of better mental health trajectories. At-risk individuals may be targeted to receive rehabilitation interventions to improve their long-term quality of life outcomes[25].
19. **Wang et al (2022)** concluded that Physical rehabilitation in the ICU improves physical function and reduces ICU and hospital length of stay. However, it does not appear to impact other outcomes[39].
20. **Bowman et al (2022)** stated that, in order to preserve continuity of treatment and offer follow-up care for any potential TBI-related sequelae, clinical pathways must be in place for all individuals who suffer a traumatic brain injury (TBI), regardless of the original severity of the injury. To meet the variety of demands of patients, several care and recovery trajectories are required. To identify the care pathways that result in the best outcomes for these various circumstances, more study is required to compare the outcomes for TBI patients who get various interventions and systems of care.[22].
21. **Campos et al (2022)** concluded that The additional application of early NMES promoted better functional status outcomes on the first day awake and at ICU and hospital discharge. The patients in the EM+NMES group also took fewer days to stand up and had shorter hospital LOS, lower frequency of ICU-acquired weakness, and better muscle strength. Future studies are still necessary to clarify the effects of therapies associated with EM, especially to assess long-term outcomes[41].

22. **Holthe et al (2022)** concluded that subjectively experienced problems with concentration and fatigue were reported by the parents of nearly half of the children. Higher brain injury symptom load was associated with lower quality of life, but was unrelated to injury severity. Two-thirds of the sample also showed abnormally large intraindividual variability in cognitive functioning. The association of brain injury symptoms with quality of life but not injury severity emphasizes the need to consider symptoms after TBI within a biopsychosocial framework[26].
23. **Nelson et al (2023)** concluded that patients with previous moderate to severe TBI (ms TBI) displayed increased independence over 5 years; msTBI was also associated with increased mortality. Their findings, in combination with the persistently elevated rates of unfavorable outcomes in mTBI vs controls imply that more monitoring and rehabilitation are needed for TBI[29].

24. **Buh et al (2023)** concluded that neurorehabilitation should start at the time of admission and continue from the intensive care unit through the community for the moderate-to-severe traumatic brain injury population. There is a need to develop, agree on, and implement guidelines on early neuro-rehabilitation interventions for patients with moderate to severe traumatic brain injury in the African region, where disparities in care are common reality.[33]
25. **Noe et al (2023)** concluded all patients with ABI should receive neurorehabilitation therapy once they present a minimal level of clinical stability. Neurorehabilitation should offer as much treatment as possible in terms of frequency, duration, and intensity (at least 45—60 minutes of each specific form of therapy that is needed). Neurorehabilitation requires a coordinated, multidisciplinary team with the knowledge, experience, and skills needed to work in collaboration both with patients and with their families. Inpatient rehabilitation interventions are recommended for patients with more severe deficits and those in the acute phase, with outpatient treatment to be offered as soon as the patient's clinical situation allows it, as long as intensity criteria can be maintained. The duration of treatment should be based on treatment response and the possibilities for further improvement, according to the best available evidence. At discharge, patients should be offered health promotion, physical activity, support, and follow-up services to ensure that the benefits achieved are maintained, to detect possible complications, and to assess possible changes in functional status that may lead the patient to need other treatment programmes[34]

SCIENTIFIC GAPS

Currently, there are no established treatment protocols since traumatic brain injuries are so unpredictable. These are often perceived as an abrupt, violent incident that results in temporary disability; nonetheless, they can have long-lasting effects. Many people who survive severe traumatic brain injury (TBI) may experience long-term physical, cognitive, and psychosocial problems and need extensive rehabilitation. Furthermore, chronic effects have been found in a percentage of cases that were previously categorized as moderate or mild, in addition to severe traumatic brain injury. In addition to having an impact on survivors' and their families' daily lives, this load has associated societal and financial implications.

Over the last few decades although mortality has been reduced owing to the presence of various clinical guidelines, still the presence of a standardized treatment protocol is the need of the hour.

OBJECTIVES

- To evaluate the effectiveness of selected rehabilitative techniques for early recovery of post-surgical brain injury patients.
- To study different combinations of above evaluated rehabilitative techniques for early recovery of post-surgical brain injury patients from neurological intensive care units.
- Validation of the combined protocol for rehabilitation of post-surgical patients.

METHODOLOGY

- ✓ **STUDY DESIGN**
    - Cross-Sequential Study Development Design (For Development of the protocols)
    - Randomized Control Clinical Trial (For analysis of the effectiveness of the designed protocol)
    - The study will be subject to approval by the University Ethics Committee (Medical), Swami Vivekanand Subharti University. The UECM is provisionally registered with National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health and Research (DHR); registration no. being EC/NEW/INST/2021/1540.

- ✓ **SAMPLING METHOD**

  Purposive Sampling

- ✓ **SAMPLE SIZE**

  385+ (at 95% confidence interval)

- ✓ **PLACE OF STUDY**

  Chattrapati Shivaji Subharti Hospital, Meerut and OPD of Jyotirao Phule Subharti College of Physiotherapy.

- ✓ **DURATION OF STUDY**

  1 year and 8 months

SELECTION CRITERIA

- ***INCLUSION CRITERIA:***
    - ✓ All patho-anatomic and patho-physiologic sequalae (Hematoma, Contusion, Sub-arachnoid hemorrhage, Ischemia, Diffused axonal injury and Vasospasm)
    - ✓ Patients aged between 16-60 years old.[2]
    - ✓ Both genders, male and female.
    - ✓ Initial GCS score at the time of admission between 8-13
    - ✓ Informed consent from patient or patients proxy(NOK/Spouse/ Sibling /Parent/Guardian) and an independent neurosurgeon.

- ***EXCLUSION CRITERIA:***
  - ✓ Patient is hemodynamically unstable.
  - ✓ Consent not given or withdrawn by the patient party.
  - ✓ History of a psychotic disorder.
  - ✓ Has a history of a progressive neurological disease.
  - ✓ Associated with spinal cord injuries.
  - ✓ History of chronic alcohol consumption or drug abuse[3].

PROCEDURE

Patients admitted to Chattrapati Shivaji Subharti Hospital, Meerut and attending the outpatient department (OPD) of Jyotirao Phule Subharti College of Physiotherapy, Meerut will be recruited. Participants who qualify eligibility criteria of the study will be required to sign an informed consent form before participation. The eligible participant will undergo a baseline (pre-intervention) measurement for study outcome measures. After this, participants will be randomly divided into experimental (Group A) and control groups (Group B). Participants of group A will receive treatment as per the protocol developed and "Group-B" shall not as it will be the control group. Post-intervention measurement for study outcomes will be taken after 6 months.

PROTOCOL

DEVELOPMENT

Exploration of various Review of Literature (ROL) associated with the study.

Collection of data for developing a standardized method of treatment.

Origination of the protocol

VALIDATION

Seek professional opinion on the protocol developed.

APPLICATION

Identification and Screening of participants as per inclusion and exclusion criteria for the study.

- Baseline Data Collection
- Obtain Consent.

Participants randomly allocated to Groups A and B. Where “Group-A” participants will receive treatment as per the protocol developed and “Group-B” shall not as it will be the control group.

Hospital Discharge Assessment.

6 Month Assessment

Data Analysis & Dissemination

OUTCOME MEASURES

DEPENDANT VARIABLES

- **Quality of Life:**

  36 items Short Form survey (SF-36) version 2, a valid and reliable scale will be used to evaluate the patient's perspective of his/ her functional health and well-being. It has 36 questions to assess the patient's physical and mental health under 8 health domains (Maruish, 2011; J. E. Ware, 2000; John E. Ware & Sherbourne, 1992). Summated raw response score will be transformed into 0 - 100 level range (Level 0 denotes the worst and 100 the best). Higher score value represents the good quality of life and better health status

- **Functional Disability:**

  The Barthel Index for Activities of Daily Living is an ordinal scale which measures a person's ability to complete activities of daily living (ADL). The Barthel Index (BI) measures the extent to which somebody can function independently and has mobility in their activities of daily living (ADL) i.e. feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation and stair climbing. The index also indicates the need for assistance in care. The BI is a widely used measure of functional disability. The index was developed for use in rehabilitation patients with stroke and other neuromuscular or musculoskeletal disorders, but may also be used for oncology patients.

STATISTICAL ANALYSIS

The collected demographic details and outcome measures will be assessed for their normality. If the data follow normal distribution, it will be expressed in descriptive statistics. Independent t test will be adopted based on normal distribution, to find out the differences between the groups. Paired t test will be adopted based on normal distribution, to find out the differences within Group-A, and Group-B for pre and post assessment outcomes. All the data will be analyzed using statistical software, statistical package for social science (SPSS), IBM SPSS version 20.0 (Armonk, NY: IBM Corp.). The p-value ≤ 0.05 will be considered to be statistically significant.

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